



[3510-16]

**DEPARTMENT OF COMMERCE**

**United States Patent and Trademark Office**

**[Docket No.: PTO-P-2013-0065]**

**Grant of Interim Extension of the Term of U.S. Patent No. 5,610,059;**

**Monovalent *Lawsonia intracellularis* bacterin vaccine**

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Notice of Interim Patent Term Extension.

**SUMMARY:** The United States Patent and Trademark Office has issued an order granting interim extension under 35 U.S.C. 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 5,610,059.

**FOR FURTHER INFORMATION CONTACT:** Mary C. Till by telephone at (571) 272-7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (571) 273-7755; or by e-mail to [Mary.Till@uspto.gov](mailto:Mary.Till@uspto.gov).

**SUPPLEMENTARY INFORMATION:** Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On December 27, 2013, the Arizona Board of Regents, on behalf of the University of Arizona, the patent owner of record, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of U.S. Patent No. 5,610,059. The patent claims the veterinary biological product monovalent *Lawsonia intracellularis* bacterin vaccine. The application indicates that Intervet, a licensee of the patent owner, submitted two Product License Applications (PLA) to the United States Department of Agriculture (USDA). In a letter dated April 12, 2011, USDA acknowledged receipt of the PLA for a multi-valent vaccine and assigned the vaccine product code 49L5.RO. In a letter dated December 22, 2011, USDA acknowledged receipt of a PLA for a monovalent vaccine of *Lawsonia intracellularis* bacterin and assigned the vaccine product code 2799.20.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because the regulatory review period will continue beyond the original expiration

date of the patent, March 11, 2014, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 5,610,059 is granted for a period of one year from the original expiration date of the patent.

Dated: February 14, 2014

Andrew Hirshfeld,  
Deputy Commissioner for Patent Examination Policy,  
United States Patent and Trademark Office.

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